Department of Pharmaceutics and Regulatory affairs

PHARMA FRONTLINE NEWS LETTER

Faculty of Pharmacy
Sri Adichunchanagiri College of Pharmacy
B.G. Nagara - 571 448, Karnataka
ADICHUNCHANAGIRI UNIVERSITY

SEPTEMBER- 2025 (BIMONTHLY) ISSUE # 11

Dept. of Pharmaceutics & Regulatory Affairs

International Pharma & Market Insights

- U.S. Tariff Policy on Imported Branded Medicines — Indian pharma's strategic adaptations.

- Automation & Robotics in Sterile Manufacturing

-Corporate sustainability initiatives and green chemistry practices in API manufacturing.

AI in Healthcare and Wound-Related Advances

- ***Artificial Intelligence in Drug Discovery and Formulation Development***
- ***AI-Guided Laser Innovations for Tumor Removal and Wound Healing***

REGUALATORY UPDATES FORUM

- *MHRA Approves EURNEFFY® — The World's First Needle-Free Adrenaline Nasal Spray*
- *Ozempic Revolutionizes Diabetes Management — Now Available in India*
- *Real-World Data Suggest Semaglutide May Outperform Tirzepatide in Cardiovascular Risk Reduction*
- *U.S. FDA Approves VIZZ (Aceclidine Ophthalmic Solution 1.44%) for Presbyopia*
- *U.S. Tariff Policy on Imported Branded Medicines — Implications for Indian Pharma*

This Issue is Edited by-

Jeewan Gowda & Rumaan M,
B. Pharma, VIII Semester, SACCP

Dhanush SP
B. Pharma, IV Semester, SACCP

MHRA APPROVES EURNEFFY® — THE WORLD'S FIRST NEEDLE-FREE ADRENALINE NASAL SPRAY

What: EURneffy® — a single-use, needle-free intranasal epinephrine spray (trade name for neffy® in Europe). GOV.UK+1.Approval date (UK): 18 July 2025 by the MHRA for emergency treatment of anaphylaxis. GOV.UK

Indication & dosing (UK): approved as a 2 mg single-dose nasal spray for the emergency treatment of serious allergic reactions in adults and adolescents weighing ≥30 kg. (US dosing/labels differ: the US label and regulatory updates include a 1 mg option for 15–30 kg children). ir.alk.net+1

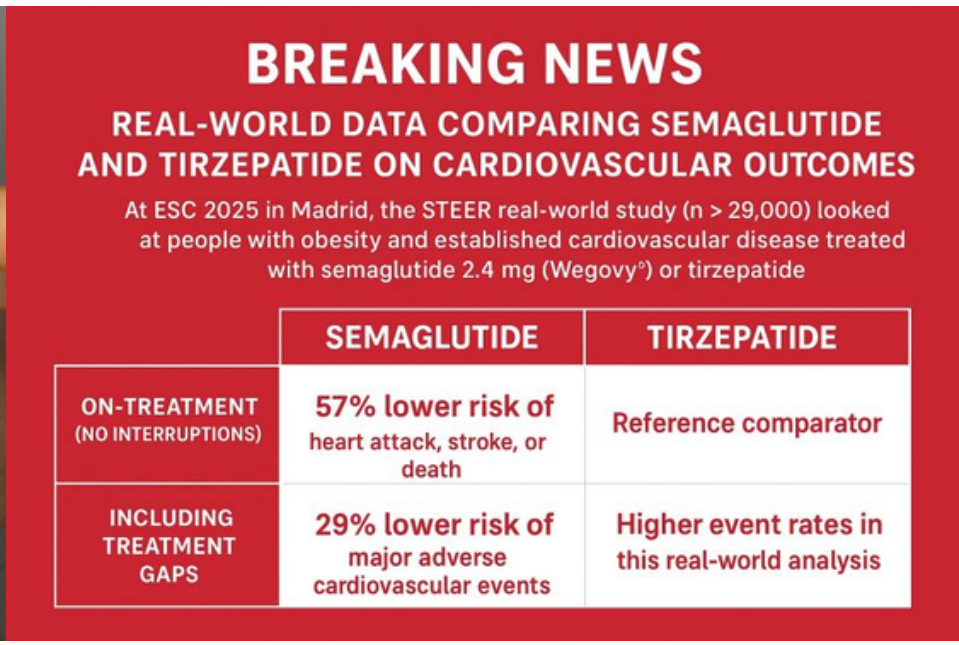
Commercial / launch: ARS Pharmaceuticals (developer) with ALK/ALK-Abelló as European marketer/co-promoter; launches expected from Q3 2025 in participating countries

Ozempic Revolutionizes Diabetes Management — Now Available in India

The Central Drugs Standard Control Organization (CDSCO) has approved Ozempic (Semaglutide), a once-weekly injectable formulation by Novo Nordisk, marking a significant advancement in India's diabetes care landscape. Semaglutide, a GLP-1 receptor agonist, works by stimulating insulin secretion when blood sugar levels are high, suppressing glucagon to reduce hepatic glucose production, and slowing gastric emptying to promote satiety and support weight management. Beyond lowering HbA1c, studies have shown semaglutide's cardiovascular and kidney benefits in certain patients with Type 2 Diabetes. Until now, only the oral form, Rybelsus, was available in India; with Ozempic's approval, patients can now access the injectable form in 0.25 mg, 0.5 mg, and 1 mg doses via a prefilled pen injector. The once-weekly dosing may improve adherence, and while mild gastrointestinal side effects like nausea or vomiting can occur, the therapy offers a powerful new tool for achieving glycemic control and weight reduction. The approval of Ozempic represents a milestone in expanding innovative treatment options and improving outcomes for millions of people living with Type 2 Diabetes in India.

A Real-World Data Suggest Semaglutide May Outperform Tirzepatide in Cardiovascular Risk Reduction

Recent real-world evidence indicates that semaglutide (marketed as Wegovy/Ozempic) may reduce the risk of major adverse cardiovascular events (MACE) more than tirzepatide (Mounjaro/Zepbound) in patients with overweight/obesity and established cardiovascular disease — particularly in those without diabetes. The findings, reported in observational studies, point toward a potentially meaningful differentiation between these two popular GLP-1 / dual-agonist therapies.



A retrospective observational study, often referred to as the STEER real-world study, compared semaglutide 2.4 mg (n ≈ 10,625) with tirzepatide in an equally sized group of patients with overweight/obesity and cardiovascular disease but no history of diabetes (NeurologyLive; Empr). The analysis found that semaglutide was associated with a 57% greater reduction in the composite risk of heart attack, stroke, and cardiovascular-related death compared with tirzepatide over the observation period (NeurologyLive; Empr). Even when accounting for small treatment gaps, semaglutide still demonstrated a 29% lower risk of these cardiovascular outcomes relative to tirzepatide (NeurologyLive; Empr). While these non-randomized, observational data cannot prove causality, they reinforce prior findings from randomized trials such as SELECT and SCORE, which linked semaglutide to cardiovascular benefits (NeurologyLive; Empr). By contrast, randomized controlled trials have consistently shown that tirzepatide produces greater weight loss than semaglutide (New England Journal of Medicine; PMC). Importantly, real-world experience often shows smaller weight reductions than clinical trials report, largely due to early discontinuation or use of lower maintenance doses (Cleveland Clinic).

Edited By-Sowmya
Ph. D Research Scholar

FDA Clears VIZZ: A Game-Changing Eye Drop for Aging Vision

The U.S. FDA has approved VIZZ (aceclidine ophthalmic solution 1.44%), a once-daily eye drop designed to treat presbyopia—the age-related decline in near vision. VIZZ works by gently constricting the pupil, creating a "pinhole effect" that enhances depth of focus and allows clearer vision for near tasks without affecting distance vision. Clinical trials (CLARITY 1–3) showed noticeable improvement within 30 minutes, lasting up to 10 hours. Mild, temporary side effects such as eye irritation, dim vision in low light, and headache were reported. Serious complications like retinal issues are rare but cautioned.The drops are expected to be available in the U.S. by late 2025, priced around $79 per month. U.S. Tariff Policy on Imported Brand.

This innovative therapy offers a non-surgical, drug-based alternative to reading glasses, potentially transforming daily vision correction for millions of adults over 40ded Medicines — Implications for Indian Pharma

Edited By-Srikruthi K
Ph. D Research Scholar

U.S. Tariff Policy on Imported Branded Medicines — Implications for Indian Pharma

The U.S. government's decision to impose 100% tariffs on imported branded and patented medicines has stirred major discussions in the global pharmaceutical sector. The move aims to promote domestic manufacturing and reduce drug costs but could significantly affect India, a key exporter of branded and generic formulations. While generic drugs are mostly exempt, uncertainty surrounds branded generics, potentially increasing export costs and reducing competitiveness.

To adapt, Indian pharma companies are exploring joint ventures, partnerships, and local manufacturing options in the U.S. to maintain market presence and avoid tariff barriers. Analysts suggest this policy may drive strategic investment diversification, encouraging firms to expand in North America while strengthening domestic operations. However, short-term effects may include price fluctuations, reduced exports, and lower profit margins. The policy highlights the growing trend toward protectionist trade measures in global healthcare markets.

Automation & Robotics in Sterile Manufacturing

Automation and robotics are transforming sterile pharmaceutical production, minimizing human intervention while boosting quality and GMP compliance. Modern facilities now use robotic filling, automated inspection, and enclosed aseptic isolators to reduce contamination risks and ensure consistent dosing.

Leading companies like Biocon and Dr. Reddy's have deployed these systems for insulin, monoclonal antibodies, and other high-value biologics, achieving higher precision and operational efficiency. AI-assisted monitoring and predictive maintenance further help detect deviations early, reduce batch failures, and improve productivity.

Closed aseptic systems also enable multi-product operations, allowing seamless switching between injectable formulations without compromising sterility. These upgrades enhance patient safety and strengthen India's position in the global sterile pharmaceuticals market.

Green Pharma in Action: Lupin & Cipla Lead Sustainable API Manufacturing

Lupin has significantly advanced its sustainability efforts by adopting green chemistry principles in API manufacturing. This approach has led to a 61% reduction in solvent and reagent consumption and a 33% decrease in the number of synthesis steps across 14 APIs. Additionally, the company has streamlined manufacturing processes, cutting solvent usage by 44% and water consumption by 75%. These measures not only minimize environmental impact but also enhance operational efficiency

Cipla has set ambitious sustainability goals, aiming to achieve carbon neutrality, water neutrality, and zero waste to landfill for its India manufacturing operations by December 2025. The company is focusing on increasing renewable energy consumption and utilizing alternative fuels to meet these targets. Additionally, Cipla has been actively involved in solvent recycling initiatives, selling mixed solvents from its API manufacturing processes to authorized recyclers, thereby promoting resource efficiency and reducing environmental impact.

Cutting-Edge Innovations in Wound Healing

Researchers in Switzerland have developed a revolutionary bandage that accelerates wound healing up to four times faster using electric stimulation, without relying on drugs or leaving scars. The bandage applies a controlled electric field to the wound, promoting tissue regeneration and improving healing outcomes. This innovation could significantly reduce recovery times and improve patient comfort.

"Skin-in-a-Syringe" Living Gel – Sweden

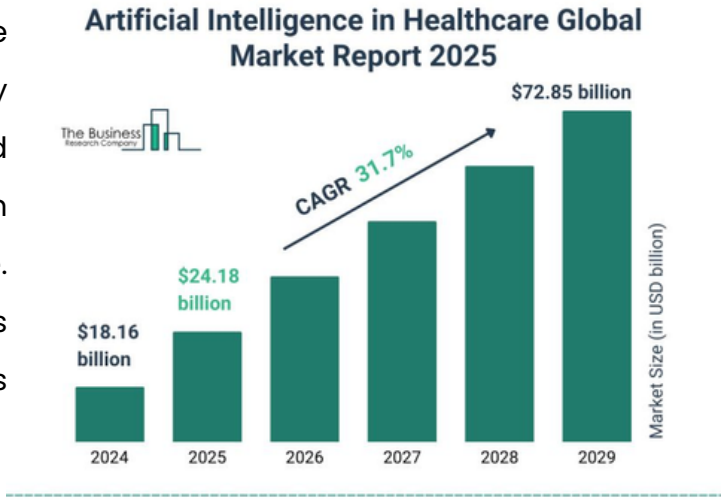
Swedish scientists have engineered a living hydrogel made from human cells, called "Skin-in-a-Syringe", which can be directly applied to wounds. This technology mimics natural skin and holds the potential to become the future of wound care, offering faster tissue regeneration and minimizing scar formation. Its adaptability could be particularly valuable for burns, chronic wounds, and surgical recovery.This advancement marks a significant step toward next-generation wound care therapies, offering hope for patients with challenging or slow-healing wounds and redefining how medical science approaches tissue repair and regeneration.

Breakthrough from Germany: A Revolutionary Gel That Regrows Joint Cartilage Naturally

A team of German researchers has reportedly developed a regenerative gel that can restore damaged joint cartilage — offering a potential alternative to surgery, implants, and long-term medication.This innovative gel works by stimulating the body's own healing mechanisms, encouraging cartilage cells to regenerate and repair worn-out tissue from within. The treatment could mark a major advancement for people suffering from arthritis, joint injuries, and age-related cartilage loss.Unlike conventional procedures such as knee replacements or invasive surgeries, this gel-based therapy promises a non-surgical, minimally invasive solution — promoting healing from the inside out.Early research suggests that patients could regain mobility, reduce pain, and improve joint function without the risks associated with implants or synthetic replacements.If proven successful in large-scale clinical trials, this innovation could redefine the future of orthopedic medicine — offering new hope for millions worldwide struggling with joint degeneration.

AI Revolution in Healthcare: A Multi-Billion Dollar Surge Transforming Global Medicine"

The global artificial intelligence (AI) in healthcare market is experiencing rapid growth, driven by advancements in machine learning, data analytics, and increasing adoption of AI-powered technologies in diagnostics, drug discovery, and patient care. According to Grand View Research, the market was valued at approximately USD 26.57 billion in 2024 and is projected to reach around USD 187.69 billion by 2030.



Similarly, MarketsandMarkets estimated the market at USD 14.92 billion in 2024, forecasting it to grow to USD 110.61 billion by 2030, reflecting a compound annual growth rate (CAGR) of about 38.6%. Fortune Business Insights presented a more optimistic projection, valuing the sector at USD 29.01 billion in 2024 with expectations to surge to USD 504.17 billion by 2032. Another analysis by Maximize Market Research estimated the market at USD 27.07 billion in 2024, potentially reaching USD 347.28 billion by 2032. Despite variations in estimates, all reports consistently highlight the transformative potential of AI in revolutionizing healthcare operations and delivering more precise, efficient, and personalized medical solutions globally.

Career Spotlight: HEOR – One of the Highest Paying Domains in Pharma

Health Economics and Outcomes Research (HEOR) has become one of the highest-paying and most in-demand fields in the pharmaceutical and healthcare industries. The surge in demand stems from a shortage of qualified experts capable of integrating economics, statistics, clinical research, and market access knowledge. HEOR professionals play a vital role in shaping healthcare policies, guiding drug pricing strategies, and ensuring the cost-effectiveness of innovative therapies. As global healthcare systems transition toward value-based and evidence-driven models, HEOR specialists have become indispensable to pharmaceutical companies, biotech firms, and consulting organizations.

Their expertise drives crucial decisions on reimbursement, patient access, and health policy development. The combination of specialized skills, strategic influence, and limited talent supply has made HEOR careers highly lucrative, offering strong international opportunities, rapid career growth, and competitive pay. Ultimately, HEOR stands at the intersection of science, economics, and policy—shaping the future of global healthcare.

REGUALATORY UPDATES FORUM

FDA Safety Update

🦠 Ixchiq Vaccine — Suspension of License

Alert: In August 2025, the FDA suspended the biologics license for Ixchiq (live-attenuated chikungunya vaccine) following reports of serious adverse events (e.g. encephalopathy).

Takeaway: Watch for further regulatory reviews and potential label revisions or market withdrawal.

📢 Drug Advertising Transparency Reform

Alert: In September 2025, HHS and the FDA introduced new rules requiring full safety warnings in all pharmaceutical advertisements (removing past loopholes).

Impact: Several companies received warning letters, including one to Eli Lilly over omission of risk disclosures for Mounjaro / Zepbound in DTC promotions.

Takeaway: Marketing teams must revise ad copy, social media, and influencer materials to comply.

🩺 Medical Device Warnings

Alert:

- FDA advised against use of unauthorized infant monitoring devices (e.g. vital sign trackers not cleared by FDA).
- Also cautioned against unapproved blood pressure devices.

Takeaway: Hospitals, clinics, and patients should confirm devices are FDA-cleared.

Other alerts: Issues flagged with implantable pumps and catheter systems (e.g. Impella controller malfunctions).

In India (CDSCO / PvPI)

💊 Drug Recall – Faulty Antidiabetic Batch

📅 August 2025

⚠️ Issue: Impurity concerns due to trace metal contamination.

🏥 Action: CDSCO ordered a nationwide recall of the affected batch; notice circulated to pharmacies and hospitals.

💡 Callout: Patients using antidiabetic medication advised to check batch numbers and consult healthcare providers.

💨 Steroid Nasal Spray Overuse Warning

📅 September 2025

⚠️ Issue: Long-term unsupervised use of nasal corticosteroid sprays beyond 3 months.

🩺 Risk: Causes nasal mucosal atrophy and potential rebound inflammation.

💡 Callout: Advisory urges stricter pharmacist oversight and prescription-based sale.

🇪🇺 European Medicines Agency (EMA)

💉 Myocarditis Signal – New mRNA Vaccine

📅 July–September 2025

⚠️ Issue: Increased myocarditis cases in young male recipients of a newly launched mRNA vaccine.

🔬 Action: EMA's PRAC strengthened safety monitoring and mandated label updates.

💡 Callout: Healthcare providers advised to monitor post-vaccination cardiac symptoms.

🧠 Medical Device Recall – Neurostimulator Software Malfunction

📅 September 2025

⚠️ Issue: Software glitch in certain implantable neurostimulator devices causing loss of therapeutic output.

🏭 Action: Manufacturer initiated voluntary recall under EMA supervision.

💡 Callout: Patients urged to contact healthcare centers for device inspection or replacement.

New Drug Approvals

💊 *Zegfrovy (Sunvozertinib) — Dizal Pharma*
Approved for EGFR exon 20 insertion–mutated non-small cell lung cancer (NSCLC) in patients previously treated with platinum-based chemotherapy.
🧠 *Quick Fact: First oral EGFR exon 20 inhibitor with demonstrated intracranial activity.* 📅*Approved: July 2, 2025*

💊 *Lynozyfic (Linvoseltamab-gcpt) — Regeneron Pharmaceuticals*
For relapsed or refractory multiple myeloma after four or more prior therapies.
🧬 *Quick Fact: Bispecific antibody targeting BCMA and CD3 — a new option for heavily pretreated patients.*
📅 *Approved: July 2, 2025*

💊 *Anzupgo (Delgocitinib) — LEO Pharma*
Treats moderate to severe chronic hand eczema in adults not adequately controlled with corticosteroids.
🌍 *Quick Fact: First topical pan-JAK inhibitor approved for hand eczema.*
📅 *Approved: July 23, 2025*

💊 *Sepiences (Sepapterin) — PTC Therapeutics*
For hyperphenylalaninemia in patients with sepiapterin-responsive phenylketonuria (PKU).
🧠 *Quick Fact: Restores tetrahydrobiopterin biosynthesis — precision metabolic therapy.*
📅 *Approved: July 28, 2025*

💊 *Vizzaceclidine — Ocuphire Pharma*
For the treatment of presbyopia (age-related near-vision loss).
🧬 *Quick Fact: Novel miotic therapy improving near vision without surgery.*
📅 *Approved: July 31, 2025*

💊 *Modeyso (Dordaviprone) — Day One Biopharmaceuticals*
Approved for diffuse midline glioma with H3 K27M mutation in patients ≥1 year old.
🧠 *Quick Fact: One of the first targeted treatments for this rare pediatric brain tumor.*
📅 *Approved: August 6, 2025*

💊 *Hernexeos (Zongertinib) — Boehringer Ingelheim*
For HER2-mutant non-small cell lung cancer following prior systemic therapy.
🌍 *Quick Fact: First selective HER2 TKI for NSCLC with proven CNS efficacy.*
📅 *Approved: August 8, 2025*

💊 *Tonmya (Cyclobenzaprine HCl Sublingual) — Tonix Pharmaceuticals*
For the management of fibromyalgia in adults.
🧬 *Quick Fact: Innovative bedtime sublingual formulation improving sleep and pain control.*
📅 *Approved: August 15, 2025*

💊 *Dawnzera (Donidalorsen) — Ionis Pharmaceuticals*
For prophylaxis of hereditary angioedema (HAE) in adults and adolescents.
💡 *Quick Fact: First antisense RNA therapy offering long-term HAE prevention.*
📅 *Approved: August 21, 2025*

💊 *Wayrilz (Rilzabrutinib) — Sanofi*
For chronic immune thrombocytopenia with inadequate response to previous treatment.
🧠 *Quick Fact: First reversible covalent BTK inhibitor approved for hematologic disorders.*
📅 *Approved: August 29, 2025*

💊 *Inlexzo (Gemcitabine Intravesical System) — Ferring Pharmaceuticals*
For BCG-unresponsive non-muscle invasive bladder cancer (NMIBC).
🌍 *Quick Fact: Localized intravesical gemcitabine delivery system enhances bladder exposure while minimizing toxicity.*
📅 *Approved: September 9, 2025*

💊 *Enbumyst (Bumetanide Nasal Spray) — Amphastar Pharmaceuticals*
For edema due to congestive heart failure, liver, or kidney disease.
💧 *Quick Fact: First intranasal loop diuretic for rapid fluid control.*
📅 *Approved: September 15, 2025*

💊 *Subvenite (Lamotrigine Oral Suspension) — Alkem Laboratories*
For epilepsy and bipolar disorder, offering flexible dosing and easy administration.
🧠 *Quick Fact: Oral suspension enables titration for pediatric and elderly populations.*
📅 *Approved: September 16, 2025*

💊 *Bosaya & Aukelso (Denosumab-kyqq) — Sandoz*
Biosimilars to Prolia/Xgeva for osteoporosis and bone metastases prevention.
🌍 *Quick Fact: First FDA-approved denosumab biosimilars expanding access to bone health therapy.*
📅 *Approved: September 16–17, 2025*

💊 *Forzinity (Elamipretide) — Stealth BioTherapeutics*
For Barth syndrome, a rare mitochondrial disorder.
🧬 *Quick Fact: Targets cardiolipin remodeling to restore mitochondrial function.*
📅 *Approved: September 19, 2025*

💊 *Keytruda Qlex (Pembrolizumab + Berahyaluronidase alfa-pmph) — Merck (MSD)*
Subcutaneous formulation of Keytruda for solid tumors where IV form is approved.
💡 *Quick Fact: First subcutaneous PD-1 inhibitor co-formulation, reducing infusion time to under 5 minutes.*
📅 *Approved: September 19, 2025*

💊 *Palsonify (Paltusotine) — Crinetics Pharmaceuticals*
For acromegaly in adults who cannot undergo surgery or have incomplete surgical response.
🧠 *Quick Fact: First oral non-peptide SST2 agonist — eliminates need for monthly injections.*
📅 *Approved: September 25, 2025*

Highlights and Students Achievements

The M.Pharm students of the Department of Pharmaceutical Regulatory Affairs actively participated in the MPCON Conference held at MAHE, Manipal, from 28th to 30th August 2025. We are especially proud that Mr. Hemanth Prasad K. P. and Mr. Dhruva R. Nadig were honored with the Best Poster Award, bringing distinction and recognition to the institution.

Best Researcher Award

The Department of Pharmaceutics is immensely proud to highlight the exceptional achievements of Mr. Chethan Patil, a postgraduate research scholar in our program. Chethan has demonstrated outstanding dedication to his field, culminating in the publication of seven research/ review articles in highly reputed international journals. This remarkable accomplishment not only showcases his expertise and hard work but also brings great honor to our department's academic standing.

Throughout his journey, Chethan's dedication never wavered. He consistently balanced coursework, laboratory work, and research writing with a positive attitude and resilience.

Chethan Patil's accomplishments have significantly strengthened our department's academic profile.

Faculty Achievements

Dr. Prakash S. Goudanavar, Dean & Principal, Sri Adichunchanagiri College of Pharmacy, served as Chairperson for a scientific session at the National Seminar on "Artificial Intelligence in Formulation Development" organized by the NITTE Institute of Pharmaceutical Sciences, Nitte (Deemed to be University), Mangalore, on 12th September 2025.

Dr. Prakash S. Goudanavar, Dean & Principal, Sri Adichunchanagiri College of Pharmacy, was honored on the occasion of the Teachers' Day celebration with an award for achieving the highest number of publications in Scopus- and Web of Science–indexed journals for the year 2024.

Dr. Raghavendra Naveen, Associate Professor, Sri Adichunchanagiri College of Pharmacy, was honored on the occasion of the Teachers' Day celebration with an award for outstanding contributions to research and publications in Scopus- and Web of Science–indexed journals for the year 2024.

Dr. Vedamurthy Joshi guided the presentation of BIOEXCIPIA – A Novel Excipient System for Solubility Solutions at the Job Fair, Career Expo & Hackathon 2025, Krupanidhi College of Pharmacy, Bangalore.The innovative concept focused on enhancing drug solubility and bioavailability through a novel excipient platform.

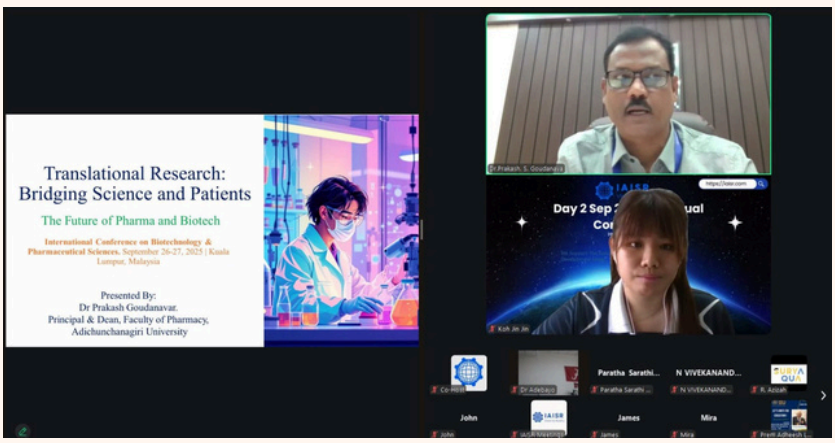
Faculty Achievements

Dr.Prakash. S Goudanavar was invited as Chief guest for one day National Seminar on AI drug discovery challenges opportunities and strategies on 14th July 2025 at Sridevi Institute of Pharmaceutical Sciences, Tumkuru-572106

Dr. Prakash Goudanavar, Principal & Dean, faculty of Pharmacy was honored with the Research Excellence Award at the 5th Convocation of Adichunchanagiri University, held on 29th July 2025.

The event was graced by the presence of Hon'ble Chancellor Sri Sri Sri Dr. Nirmalanandanath Swamiji, Dr. S. Somanath, Former Chairman of ISRO, and Mr. Cheluvarayaswamy, Hon'ble Minister for Agriculture, Government of Karnataka.

Dr.Prakash. S Goudanavar has delivered a talk on Integrating AI and digital therapeutics: Advancing Patent Centric Healthcare at School of Pharmacy International Medical School, Faculty of Health and Life Sciences at 24th International Medical, Pharmaceutical, Cosmoceutical, and Health science Cosmeceutical, and Health Science Symposium (iMPaCHS 2025) held at Management and Science University (MSU), Malaysia on 3rd July 2025. He delivered an impactful presentation on: "AI in Pharmacy: Transforming Drug Development, Dispensing, and Patient Outcomes.



·Dr. Prakash S. Goudanavar delivered an insightful presentation on the topic "Translational Research: Bridging Science and Patients – The Future of Pharma and Biotech,during the International Conference on Biotechnology & Pharmaceutical Sciences was held virtually from September 26 to 27, 2025, with its official venue based in Kuala Lumpur, Malaysia.

MoU Signing Ceremony: Strengthening Academic Ties in Regulatory Affairs

The Department of Pharmaceutics & Regulatory Affairs, Faculty of Pharmacy, Sri Adichunchanagiri College of Pharmacy (SACCP), B.G. Nagara, organized an MoU Signing Ceremony on 14th July 2025 at the SACCP Lecture Hall. The event focused on the theme "Academic Collaboration and Advancing Regulatory Affairs Research."

The Memorandum of Understanding (MoU) was formally signed between SACCP and Manipal College of Pharmaceutical Sciences (MCOPS), establishing a partnership aimed at promoting joint research initiatives, academic cooperation, and knowledge exchange in the field of pharmaceutical regulatory affairs.

The event's highlight was an insightful expert session by Dr. D. Sreedhar, Professor and Head, Department of Pharmaceutical Regulatory Affairs and Management, MCOPS, Manipal Academy of Higher Education. His address emphasized the growing importance of academia–industry collaboration and the evolving scope of regulatory sciences.

Workshop on "Navigating the Global Regulatory Landscape"

The Department of Pharmaceutics & Regulatory Affairs, Sri Adichunchanagiri College of Pharmacy (SACCP), organized a workshop titled "Navigating the Global Regulatory Landscape: Industry Insights for Future Professionals" on 12th July 2025 at the Yuvalaya Auditorium, Adichunchanagiri University, B.G. Nagara.

Eminent industry experts from Strides Pharma Ltd. — Mr. Selvakumar Subramanian, Mr. J. Ashok Kumar, Mr. Janardhan Ramakrishna, and Mr. Andanesh C.B. — shared valuable insights into global regulatory practices, recent developments, and evolving career opportunities in the pharmaceutical regulatory domain.

The session provided postgraduate and undergraduate students with a deeper understanding of international regulatory frameworks and industry expectations, bridging the gap between academic learning and professional practice.

Publications & Book Chapters

Investigational New Drugs
https://doi.org/10.1007/s10637-025-01562-3

REVIEW

Advanced strategies to overcome multidrug resistance in cancer therapy: progress in P-glycoprotein inhibitors, drug delivery, and personalized medicine

Ankitha Harish[1] · N. Deepika[1] · Vedamurthy Joshi[1] · Prakash S. Goudanavar[1]

Received: 8 May 2025 / Accepted: 2 July 2025

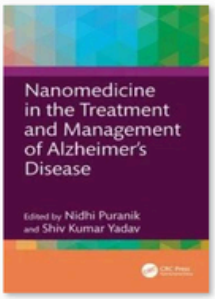
Summary
Multidrug resistance (MDR) appears to be a major challenge in cancer treatment, frequently leading to suboptimal clinical results and treatment failure. A transmembrane efflux pump called P-glycoprotein (P-gp) is essential to multidrug resistance because it actively transports various chemotherapeutic drugs out of cancer cells, lowering their intracellular concentrations and efficacy. To improve treatment approaches, it is essential to comprehend the structural and functional dynamics of P-glycoprotein and the genetic and epigenetic processes controlling its expression. From the early-generation drugs with poor clinical outcomes to the creation of new medications with enhanced selectivity, potency, and safety profiles, this article thoroughly summarizes the development of P-glycoprotein inhibitors. Enhancing medication bioavailability and overcoming P-glycoprotein-mediated efflux may be possible through the integration of sophisticated drug delivery methods, such as micellar formulations, liposomes, nanoparticles, and polymer-based carriers. Meanwhile, the rise of personalized medicine provides a revolutionary way to manage multidrug resistance through identifying biomarkers, genetic and proteomic characterization, and medication modification for each patient. Advanced tactics such as RNA interference, CRISPR-mediated gene editing, immunotherapeutic therapies, and tumor microenvironment modulation significantly broaden the options to counter multidrug resistance. While highlighting current difficulties, case studies and clinical examples also illustrate translational achievements. In addition to highlighting recent advancements, the present research points out important constraints and suggests potential paths for more potent, focused multidrug resistance cancer treatments.

Keywords Multidrug resistance (MDR) · P-glycoprotien(P-gp) · Cancer therapy · Chemoresistance · Tumor heterogeneity · Personalized medicine

Chapter 16

Nanocarrier-Based Delivery of Biologics for Retinal and Posterior Segment Eye Diseases

Shithin Ann Varghese[1]
M. Sruthi Laakshmi[2]
Srikruthi Kunigal Sridhar[1]
Prakash Goudanavar[1]
Santhosh Fattepur[3]
and Nimbagal Raghavendra Naveen[1,*]
[1]Department of Pharmaceutics, Sri Adichunchanagiri College of Pharmacy, B. G. Nagara, Mandya, India
[2]Department of Pharmaceutics, SRM College of Pharmacy, SRMIST, Kattankulathur, Tamil Nadu, India
[3]School of Pharmacy, Management and Science University, Seksyen 13, Shah Alam, Selangor, Malaysia



Chapter

Challenges and Opportunities of Nanomedicines in Clinical Translation

By Meenakshi Kumari, Nagaraja Sreeharsha, Prakash Goudanavar, Bharti Sahu, Nidhi Puranik, Arun Sharma

Book Nanomedicine in the Treatment and Management of Alzheimer's Disease

Edition	1st Edition
First Published	2025
Imprint	CRC Press
Pages	24

Regenerative Engineering and Translational Medicine
https://doi.org/10.1007/s40883-025-00497-8

REVIEW

Bioengineered Scaffolds and 3D Printing in Wound Healing: Innovative Strategies for Chronic Wound Management

Praveen H S[1] · Prasiddhi Naik[1] · Prakash Goudanavar[1]

Received: 21 May 2025 / Revised: 19 August 2025 / Accepted: 3 September 2025

Abstract
Wound healing is a complex and dynamic biological process characterized by several distinct yet interconnecte
haemostasis, inflammation, proliferation, and remodelling. Chronic wounds, especially in diabetic and elderly in
pose ongoing challenges due to factors such as infection, biofilm development, and slow tissue regeneration. T
treatments, including surgical debridement and antibiotic therapy, frequently fall short because of antimicrobial
and their inability to tackle the underlying pathophysiological issues. Recent progress in nanotechnology, biomate
regenerative medicine has led to the development of novel approaches, such as bioengineered scaffolds, smart h
and 3D-printed constructs, which provide structural support and enable the controlled release of bioactive substan
natural and synthetic polymers, including chitosan, collagen, PEG, and PLGA, have been widely utilized to impro
healing by enhancing biocompatibility, antimicrobial effectiveness, and mechanical strength. The incorporation of
ticles like silver, zinc oxide, and lipid-based carriers further enhances antibacterial properties and drug delivery
Advanced manufacturing techniques, such as electrospinning and stereolithography, allow for the precise creation
dressings that replicate the extracellular matrix, thereby promoting cellular adhesion and angiogenesis. Additio
driven scaffold design and personalized medicine strategies, including 3D bioprinting and bioactive hydrogel sy
transforming the landscape of wound care by enabling tailored treatments that respond to specific physiological c
of the wound. Despite significant advancements, challenges related to large-scale production and regulatory co
continue to pose major obstacles. Overcoming these issues is crucial for translating laboratory advancements into
ized clinical applications. In summary, the integration of nanotechnology, bioengineering, and personalized me
the potential to significantly advance the management of chronic wounds.

Home › Medical Oncology › Article

Advanced nanotheranostic approaches for targeted glioblastoma treatment: a synergistic fusion of CRISPR-Cas gene editing, AI-driven tumor profiling, and BBB-modulation

Review Article | Published: 07 August 2025
Volume 42, article number 413, (2025) Cite this article

Medical Oncology
Aims and scope →
Submit manuscript →

Download PDF

Chethan Patil, R. Priyanka, B. M. Harshitha, S. Oshik, S. Yashwanth, B. R. Darshan, Shradha Patil, K. A. Prajwal, Prasiddhi Naik, Prakash Goudanavar & T. Mallamma

143 Accesses 15 Altmetric 2 Mentions Explore all metrics →

Abstract

Glioblastoma (GBM) is the most aggressive primary brain tumor in adults. It is hard to treat because it is very invasive, has a lot of genetic variation, and the blood–brain barrier (BBB) limits its growth. Traditional GBM treatments, including surgery, radiation and chemotherapy have only marginally improved survival requiring a paradigm shift. This review starts a new way of thinking about how to treat GBM by combining multi-

Home › Biomedical Materials & Devices › Article

Physicochemical Engineering of Phyto-Nanotherapeutics for Precision-Targeted Therapy in Skin Cancer

Review | Published: 05 August 2025
(2025) Cite this article

Biomedical Materials & Devices
Aims and scope →
Submit manuscript →

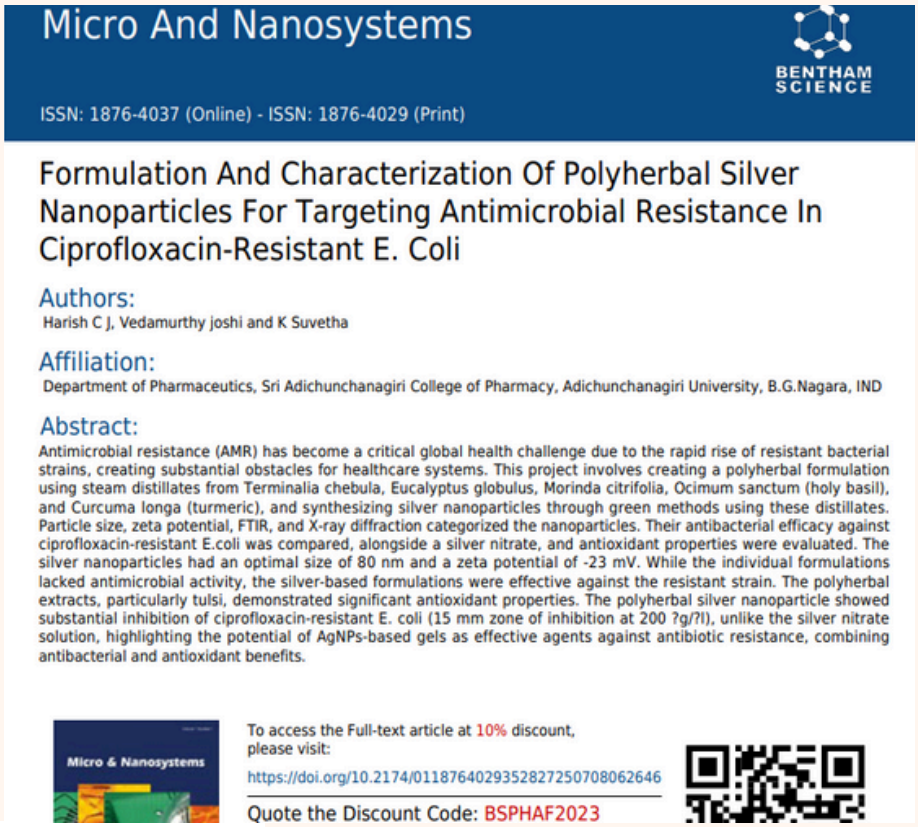
Chethan Patil, S. Oshik, S. Yashwanth, B. R. Darshan, M. Yashwanth, G. N. Vishwas, B. J. Yashwanth, D. Mohan Kumar, Prasiddhi Naik & Prakash Goudanavar

14 Accesses Explore all metrics →

Abstract

The intricate aspects of tumor biology, the diverse tumor microenvironment, and the challenges posed by conventional chemotherapy contribute to the complexities of managing skin cancer. Phytonanomedicine (PNM) is an innovative cancer treatment strategy that integrates bioactive compounds derived from plants with nanoscale delivery systems. This paper provides a detailed examination of the complex physical and chemical interactions of nanocarriers and their essential contribution to enhancing the distribution of plant-based medicines, skin penetration, and focused accumulation. The study showcases the potential of tailored nanoformulation to navigate biological obstacles, modify tumor microenvironments, and boost immunomodulatory and apoptotic mechanisms through the manipulation of nanoparticle size, surface properties, responsiveness to stimuli, and ligand-directed movement. Topics covered in this study include herbal nanocarrier-based drug delivery systems for skin cancer, tumor biology and microenvironment,

Patents and Publications



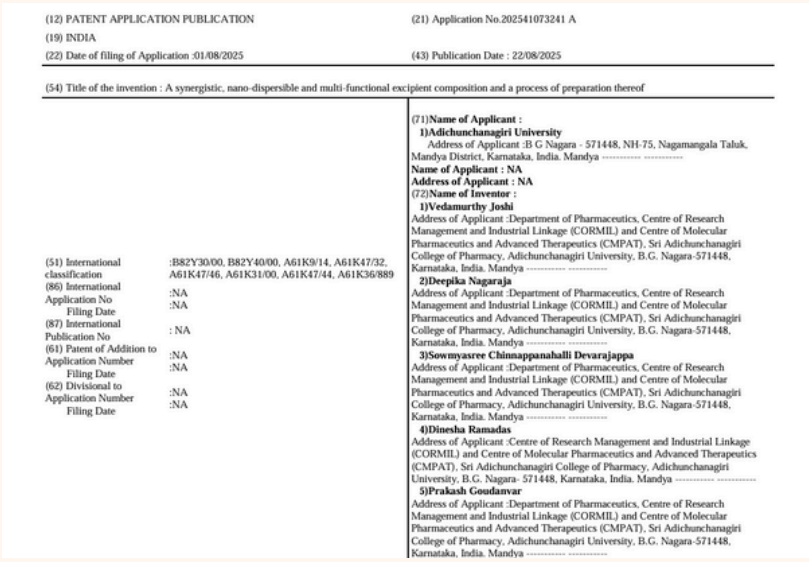
(12) PATENT APPLICATION PUBLICATION
(19) INDIA
(22) Date of filing of Application :02/07/2025
(21) Application No.202541063265 A
(43) Publication Date : 11/07/2025

(54) Title of the invention : PREPARATION AND CHARACTERIZATION OF HERBO SYNTHETIC NANOCONJUGATE FORMULATIONS FOR ENHANCED ANTIMICROBIAL ACTIVITY

(51) International classification :A61P0031040000, A61K0033380000, A61K0009000000, A61K0009510000, B82Y0040000000
(86) International Application No :NA
Filing Date :NA
(87) International Publication No : NA
(61) Patent of Addition to Application Number :NA
Filing Date :NA
(62) Divisional to Application Number :NA
Filing Date :NA

(71)Name of Applicant :
1)Moumita Banerjee
Address of Applicant :Research Scholar, Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University, BG Nagara, Nagamagala, Mandya, Karnataka, 571418, India. Nagamagala
2)Dr Vedamurthy Joshi
3)Dr. Suresh Janadri
Name of Applicant : NA
Address of Applicant : NA
(72)Name of Inventor :
1)Moumita Banerjee
Address of Applicant :Research Scholar, Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University, BG Nagara, Nagamagala, Mandya, Karnataka, 571418, India. Nagamagala
2)Dr Vedamurthy Joshi
Address of Applicant :Professor, Faculty of Pharmacy, Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University, BG Nagara, Nagamagala, Mandya, Karnataka, 571418, India. Nagamagala
3)Dr. Suresh Janadri
Address of Applicant :Associate Professor, Department of Pharmacology, Acharya and BM Reddy College of Pharmacy, Acharya Dr. Sarvepalli Radhakrishnan Road, Acharya Post Office, Soldevanahalli, Hessarghatta Road, Bengaluru, Karnataka, 560107, India. Bengaluru

Patent Application Publication
Application No.:202541063265 A
Country: India
Date of Filing of Application: 02/07/2025
Publication Date: 11/07/2025
Title of the Invention:
Preparation and Characterization of Herb-Synthetic Nanoconjugate Formulations for Enhanced Antimicrobial Activity



(12) PATENT APPLICATION PUBLICATION
(19) INDIA
(22) Date of filing of Application :01/08/2025
(21) Application No.202541073241 A
(43) Publication Date : 22/08/2025

(54) Title of the invention : A synergistic, nano-dispersible and multi-functional excipient composition and a process of preparation thereof

(51) International classification :B82Y30/00, B82Y40/00, A61K9/14, A61K47/32, A61K47/46, A61K31/00, A61K47/44, A61K36/889
(86) International Application No :NA
Filing Date :NA
(87) International Publication No : NA
(61) Patent of Addition to Application Number :NA
Filing Date :NA
(62) Divisional to Application Number :NA
Filing Date :NA

(71)Name of Applicant :
1)Adichunchanagiri University
Address of Applicant :B G Nagara - 571448, NH-75, Nagamangala Taluk, Mandya District, Karnataka, India. Mandya
Name of Applicant : NA
Address of Applicant : NA
(72)Name of Inventor :
1)Vedamurthy Joshi
Address of Applicant :Department of Pharmaceutics, Centre of Research Management and Industrial Linkage (CORMIL) and Centre of Molecular Pharmaceutics and Advanced Therapeutics (CMPAT), Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University, B.G. Nagara-571448, Karnataka, India. Mandya
2)Deepika Nagaraja
Address of Applicant :Department of Pharmaceutics, Centre of Research Management and Industrial Linkage (CORMIL) and Centre of Molecular Pharmaceutics and Advanced Therapeutics (CMPAT), Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University, B.G. Nagara-571448, Karnataka, India. Mandya
3)Sowmyasree Chinnappanahalli Devarajappa
Address of Applicant :Department of Pharmaceutics, Centre of Research Management and Industrial Linkage (CORMIL) and Centre of Molecular Pharmaceutics and Advanced Therapeutics (CMPAT), Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University, B.G. Nagara-571448, Karnataka, India. Mandya
4)Dinesha Ramadas
Address of Applicant :Centre of Research Management and Industrial Linkage (CORMIL) and Centre of Molecular Pharmaceutics and Advanced Therapeutics (CMPAT), Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University, B.G. Nagara- 571448, Karnataka, India. Mandya
5)Prakash Goudanvar
Address of Applicant :Department of Pharmaceutics, Centre of Research Management and Industrial Linkage (CORMIL) and Centre of Molecular Pharmaceutics and Advanced Therapeutics (CMPAT), Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University, B.G. Nagara-571448, Karnataka, India. Mandya

Patent Application Publication
Application No.: 202541073241 A
Country: India
Date of Filing of Application: 01/08/2025
Publication Date: 22/08/2025
Title of the Invention:
A Synergistic, nano-dispersible and multi-functional excipient composition and a process of preparation thereof.

Our Team

Dr. Prakash S Goudanavar, Professor & Head

Dr. Vedamurthy Joshi, Professor

Dr. Madhu B K, Assistant Professor

Dr. Prasiddhi Naik, Assistant Professor

Dr. Kiran Kumar G B, Professor

Dr. Naveen Raghavendra, Associate Professor

Dr. Mallamma T, Assistant Professor

Mr. Suhas N S, Assistant Professo